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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David P. Jackson

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EXAMINER

HENKEL, DANIELLE B

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,427	Applicant(s) JACKSON ET AL.	
	Examiner DANIELLE HENKEL	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29, 31, 34, 35, 39, 41, 42, 45, 52-55, 58-60, 63-65 and 93-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31, 34-35, 39, 41-42, 45, 52-55, 58-60, 63-65, and 93-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2009 has been entered.
2. Claims 26-29, 31, 34-35, 39, 41, 42, 45, 52-55, 58-60, 63-65, and 93-112 remain pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 26-29, 31, 34, 52-53, 59, 63-64, 93-97, 103-104, 108, and 110-112 are rejected under 35 U.S.C. 102(e) as being anticipated by HEI (Us 6962714).
 - a. With respect to claim 26, HEI discloses a method of cleaning (Column 21, line 63) an object with a densified fluid (gas, substantially non-aqueous) by

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forming a composition comprising percarbonic acid (Column 16, lines 16-19), then contacting the object with the fluid (Column 20, line 55- Column 21, line 22) under a specific pressure and temperature (conditions conducive to removing contaminants) (Column 21, lines 23-62).

b. With respect to claim 27, HEI discloses the contaminants are microorganisms (biological) (Column 26, lines 27-46).

c. With respect to claim 28, HEI discloses a method of disinfecting an object (Column 26, lines 27-46) with a densified fluid (gas, substantially non-aqueous) by forming a composition comprising percarbonic acid (Column 16, lines 16-19), then contacting the object with the fluid (Column 20, line 55- Column 21, line 22) under a specific pressure and temperature (conditions conducive to removing contaminants) (Column 21, lines 23-62).

d. With respect to claim 29, HEI discloses a method of cleaning (Column 21, line 63) and disinfecting an object (Column 26, lines 27-46) with a densified fluid (gas, substantially non-aqueous) by forming a composition comprising percarbonic acid (Column 16, lines 16-19), then contacting the object with the fluid (Column 20, line 55- Column 21, line 22) under a specific pressure and temperature (conditions conducive to removing contaminants) (Column 21, lines 23-62).

e. With respect to claim 31, HEI discloses the contaminants are microorganisms (biological) (Column 26, lines 27-46).

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- f. With respect to claim 34, HEI discloses the fluid comprises densified carbon dioxide (Column 16, lines 16-59), in which HEI defines "densified" as referring to a fluid in a supercritical state (Column 2, lines 55-59).
- g. With respect to claim 52, HEI discloses the fluid further comprises at least one additive (Column 2, lines 12-18).
- h. With respect to claim 53, HEI discloses the additive is hydrogen peroxide (Column 16, lines 16-19).
- i. With respect to claim 59, HEI discloses the substrate is composed of metal, ceramic, glass and polymers (Column 22, line 35- Column 23, line 20).
- j. With respect to claim 63-64, HEI discloses the substrate is a medical device including those with tubing, related to catheters and cannulas (Column 5, lines 39-57).
- k. With respect to claim 93, HEI discloses the densified (substantially non-aqueous) fluid comprising percarbonic acid is formed by contacting the components that form the antimicrobial agent (hydrogen peroxide) (Column 28, lines 25-26) in the presence of the densified fluid (carbon dioxide) (Column 1, line 67) and heating (under condition conducive to formation) and further draining off residual liquid (aqueous phase) reactants to form densified fluid comprising percarbonic acid (Column 17, lines 17-45).
- l. With respect to claim 94, HEI discloses draining off residual liquid reactants (percarbonic acid phase separated from aqueous phase) to dry and form a densified fluid comprising percarbonic acid (Column 17, lines 41-45).

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- m. With respect to claim 95, HEI discloses a method of cleaning (Column 21, line 63) and disinfecting an object (Column 26, lines 27-46) with a densified fluid (gas, substantially non-aqueous) by forming a composition comprising percarbonic acid (Column 16, lines 16-19), then contacting the object with the fluid (Column 20, line 55- Column 21, line 22) under a specific pressure and temperature (conditions conducive to removing contaminants) (Column 21, lines 23-62).
- n. With respect to claim 96, HEI discloses the contaminants are microorganisms (biological) (Column 26, lines 27-46).
- o. With respect to claim 97, HEI discloses the fluid comprises densified carbon dioxide (Column 16, lines 16-59), in which HEI defines "densified" as referring to a fluid in a supercritical state (Column 2, lines 55-59).
- p. With respect to claim 103, HEI discloses the fluid further comprises at least one additive (Column 2, lines 12-18).
- q. With respect to claim 104, HEI discloses the additive is hydrogen peroxide (Column 16, lines 16-19).
- r. With respect to claim 108, HEI discloses the substrate is composed of metal, ceramic, glass and polymers (Column 22, line 35- Column 23, line 20).
- s. With respect to claim 110-112, HEI discloses the substrate is a medical device including those with tubing, related to catheters and cannulas (Column 5, lines 39-57).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 60 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEI (US 6962714)

a. With respect to claims 60 and 109, HEI discloses the claimed invention except for the specific material comprising the substrate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a substrate composed of a specific material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In addition, the many devices and objects for

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treatment disclosed by HEI (Column 22, line 35- Column 23, line 20) are known to be composed of one or a combination of the specific materials listed in claim 60.

8. Claims 35, 39, 98-99, 58 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEI (US 6962714) as applied to claims 26-29, 31, 34, 52-53, 59, 63-64, 93-97, 103-104, 108, and 110-112 above, and further in view of CAPUTO (US 5244629).

a. With respect to claim 35 and 98, HEI does not explicitly disclose the method wherein the fluid and object are contacted with plasma. However, CAPUTO discloses a method of sterilizing all types of articles used in the healthcare environment by contacting the article with gaseous peracid antimicrobial agents (fluid comprising non-aqueous percarbonic acid) and exposing the article to a plasma treatment (Column 2, line 52- Column 3, line 24). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the method of HEI to include the plasma treatment as taught by CAPUTO because peracid vapors are known to not achieve complete sterilization for many types of articles requiring sterilization, and most produce damage to articles and packaging in the course of producing high sterilization results and exposure to plasma gas reliably and more efficiently kills resistant spores at conditions which are not destructive to packaging materials and

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therefore provides an all purpose, effective sterilizing system and process (Column 2, lines 45-51 and Column 4, lines 34-47).

b. With respect to claims 39 and 99, CAPUTO discloses a method of sterilizing a substrate with plasma that contains ultraviolet emissions (UV irradiation) and without a large component of ions (weakly ionized) because it allows for effective sterilization without corrosion of the substrate due to high concentrations of ions (Column 7, lines 28-49).

c. With respect to claims 58 and 107, HEI does not explicitly disclose the step of drying the substrate after contacting it with fluid. However, CAPUTO discloses the method comprising the step of evacuating (drying) the article sterilization chamber after contacting the article with the fluid because it allows for the proper plasma sterilization treatment of the article (Column 3, lines 1-16).

9. Claims 41-42, 45, 54-55, 100-102, and 105-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEI (US 6962714) as applied to claims 26-29, 31, 34, 52-53, 59, 63-64, 93-97, 103-104, 108, and 110-112 above, and further in view of CHAO (US 5996155).

a. With respect to claim 41 and 100, HEI does not explicitly disclose the fluid and substrate being irradiated with UV light during contact. However, CHAO teaches a method of sterilizing a substrate in a chamber in contact with liquid carbon dioxide and hydrogen peroxide while being exposed (irradiated) to an ultraviolet radiation source (Column 8, line 58- Column 9, line 4). At the time of

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the invention it would have been obvious to one of ordinary skill in the art to modify the sterilization system of HEI to include the irradiation with UV light as taught by CHAO because UV light has proven benefits in disinfecting solid surfaces by controlling pathogens without the use of harmful chemicals (Column 3, lines 23-27).

b. With respect to claim 42 and 101, CHAO teaches using UV radiation that is preferably within the range of about 180 to 300 nm (at least 40% wavelength less than 300 nm) (Column 5, lines 44-45) because it disrupts the DNA strands of micro-organisms and prevents cell replication causing death, and microbes are vulnerable to the effects of light in this range because it breaks organic molecular bonds causing cellular and genetic damage to microorganisms (column 3, lines 25-36).

c. With respect to claim 45 and 102, CHAO teaches UV radiation may be produced from lamps in continuous or high energy bursts depending upon which is suitable for cleaving specific contaminant bonds (Column 5, lines 54-56).

d. With respect to claims 54-55 and 105-106, HEI does not disclose translating the substrate during contact with the fluid. However, CHAO teaches translating the fluid in respect to a stationary substrate because the movement is necessary for cleaning specifically transport and distribution of chemical oxidants needed for sterilization and disinfection to contact all portions of the substrate (Column 8, lines 39-57). At the time of the invention it would have been obvious to one of ordinary skill in the art to translate the substrate instead of the fluid,

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since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Response to Arguments

10. Applicant's arguments with respect to claims 26-29, 31, 34-45, 49, 41-42, 52-55, 58-60, 63-65, and 93-112 have been considered but are moot in view of the new ground(s) of rejection over HEI (US 6962714) above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/
Examiner, Art Unit 1797

/William H. Beisner/
Primary Examiner, Art Unit 1797